

**RECONSIDERATION EVALUATION OF THE APPLICATION SUBMITTED ON
BEHALF OF SOUTHWEST WASHINGTON MEDICAL CENTER PROPOSING TO
ESTABLISH A NEONATAL INTENSIVE CARE NURSERY AND LEVEL III
OBSTETRIC SERVICES AT THE HOSPITAL**

PROJECT DESCRIPTION

Health Systems Group is a Washington non-profit corporation, and the sole member of Southwest Washington Medical Center (SWMC). SWMC is a Washington private, not-for-profit corporation and a 501(c)(3) exempt organization. SWMC is a hospital located at 400 Northeast Mother Joseph Place in the city of Vancouver, within Clark County. SWMC provides Medicare and Medicaid acute care services at the following two sites under a single hospital license.

Southwest Washington Medical Center	400 Northeast Mother Joseph Place, Vancouver
Memorial Health Center ¹	3400 Main Street, Vancouver

SWMC is currently licensed for 360 acute care beds,² holds a three-year accreditation from the Joint Commission on Accreditation of Health Care Organizations, and is designated as a level II trauma hospital and trauma rehabilitation hospital.

Additionally, SWMC operates a Medicare certified hospice agency, known as Hospice Southwest, and Hospice Southwest operates a 20 bed hospice care center. Both facilities are also located in the city of Vancouver. [source: CN historical files]

Currently, SWMC has a special care nursery within space at the hospital that provides a full range of maternal and neonatal services for uncomplicated patients and for the majority of complicated obstetrical problems. For CN purposes, this service is known as "level II obstetric services" or simply "level II services." [source: Application, Executive Summary]

This application proposes to establish a neonatal intensive care unit (NICU) and level III obstetric services within space at SWMC. A level III obstetric service is offered in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communication, transfer, and transportation for level III patients in a given region. Level III services include the provision of leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research. Hereinafter, the proposed program will be referred to as "level III services." [source: Washington Administrative Code 246-310-020]

SWMC has already made the capital and operating investments to expand and remodel its current 10-bed level IIB special care nursery. The special care nursery remodel was primarily

¹ Only psychiatric beds are located at the Memorial Health Center site.

² On April 8, 2002, SWMC was issued CN #1241 approving the addition of 82 beds to the existing 360 acute care beds, for a facility total of 442 acute care beds. As of the writing of this evaluation, SWMC has not completed implementation of CN #1241.

funded through a \$2.4 million philanthropic donation. The remodel allowed SWMC to expand the special care nursery from 10 to 18 beds. This expansion would accommodate the proposed level III services, and allow SWMC to provide services for a total of 18 level II or III infants. [source: Application, p8 and Executive Summary]

SWMC has partnered with Oregon Health & Science University (OHSU) and Oregon Health & Science University Medical Group (OHSUMG) for this project. SWMC states that combining efforts of OHSU and OHSUMG with the hospital will assist SWMC with the operations of its current level II services and development of the proposed level III services. [source: Application, p6]

If this project is approved, SWMC anticipates its level III services would be offered within one year of approval. [source: Application, p9] Under this timeline, year 2008 would be SWMC's first full calendar year of operation as a level III provider. At project completion, SWMC would have the capacity for 18 infants requiring either level II or level III services. [source: Application, Executive Summary]

The capital expenditure associated with the establishment of SWMC's proposed level III services is \$50,000, which includes only the fees for submission of the application. [source: Application, p29] This project does not propose to increase the total acute care licensed bed capacity at SWMC, within Clark County, or within Washington State as a whole.

BACKGROUND INFORMATION ON THE PROJECT

On April 21, 2006, the department denied SWMC's request to establish a neonatal intensive care unit (NICU) and level III obstetric services within space at SWMC. The denial was based on SWMC's failure to meet the criteria related to need, financial feasibility, structure and process of care, and cost containment.

On May 17, 2006, SWMC submitted its "Request for Reconsideration" related to the department's denial, which included information related to the criteria denied.³ The department granted SWMC's reconsideration request, and on September 28, 2006, conducted a public hearing and received additional clarifying information from SWMC, as well as comments from any affected persons. On October 13, 2006, the department allowed SWMC and affected persons to submit rebuttal comments related to any comments received at the public hearing. This document is the evaluation of the reconsideration information.

Within the reconsideration documentation, SWMC references its "current" 18-bed special care nursery. As stated above, when SWMC submitted this application on July 28, 2005, SWMC identified a 10-bed special care nursery, and if allowed to expand to level III services, SWMC would expand the special care nursery by 8 beds, resulting in an 18 bed special care nursery. The initial application indicated that the special care nursery expansion would occur regardless of whether SWMC was approved to expand its current level II services to include level III services. As of the writing of this evaluation, SWMC has completed its special care nursery expansion, which includes an increase of space for level II bassinets from 10 to 18. It is noted

³ WAC 246-310-560.

that Department of Health Construction Review Services did not approve the additional space to level III standards.⁴ Further, SWMC did not receive prior Certificate of Need approval to increase its bed capacity by an additional 8 beds. The 8 bed addition to the NICU level II was accomplished by a redistribution of SWMC's current licensed bed capacity of 360. As a result, the hospital is currently using is licensed beds as follows: 18 level II beds, 312 acute care beds; 16 psych beds; and 14 rehab beds. [source: CRS Letter of Transmittal, CRS project #8164; SWMC November 4, 2005, hospital license application]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(C).

Within its May 17, 2006, reconsideration request, SWMC submitted arguments asserting that SWMC has been providing level IIIA neonatal services on a regular basis since year 2004, and therefore, submission of this application in year 2005 to establish its level III services was not required. On November 6, 2001, SWMC submitted to the Certificate of Need Program a Determination of Reviewability (DOR) request related to SWMC's proposed offering of level III services. In that request, SWMC stated that it "*currently offers intermediate care nursery and obstetric services level II, and is licensed to offer ten neonatal intensive care beds.*" The letter further stated that "*SWMC would like to enhance its capacity to offer level III patient care*" and requested the Program allow SWMC to expand its services without prior review and approval. On February 5, 2002, the Program responded to SWMC's DOR request and concluded that SWMC was currently providing level II obstetric services, and prior Certificate of Need review and approval was required before SWMC could expand its services to include level III. As a result, if SWMC is currently providing, and has been providing, level IIIA neonatal services on a regular basis since year 2004 as it asserts in its May 17, 2006, reconsideration request, SWMC has been and is providing a service without obtaining the proper Certificate of Need authority in violation of RCW 70.38. SWMC must cease providing level IIIA neonatal services until it receives the proper authority to provide those services.

APPLICATION CHRONOLOGY

Initial Review

July 28, 2005

September 22, 2005

September 23, 2005, through

January 2, 2006

January 3, 2006

Letter of Intent Submitted

Application Submitted

Department's Pre-Review Activities

- 1st screening activities and responses
- 2nd screening activities and responses

Department Begins Review of the Application

- public comments accepted throughout review
- no public hearing requested or conducted

⁴ On May 24, 2006, Construction Review Services denied SWMC's request for an exemption related to the square footage of SWMC's NICU for level III services. If this project is approved, SWMC would have to submit a new exemption request to CRS if it elects to accommodate the NICU services in its current space.

APPLICATION CHRONOLOGY

Initial Review (continued)

March 7, 2006	Rebuttal Documents Submitted to Department
April 21, 2006	Department's Anticipated Decision Date
April 21, 2006	Department's Actual Decision Date

Reconsideration Review

May 17, 2006	Applicant Submits Request for Reconsideration, including supplemental documentation
June 16, 2006	Department Grants Reconsideration
September 28, 2006	Reconsideration Public Hearing Conducted in Vancouver
	Information Submitted by Applicant & Affected Person
October 13, 2006	Rebuttal Documents Received at Department
November 27, 2006	Department's Anticipated Reconsideration Decision Date
November 27, 2006	Department's Actual Reconsideration Decision Date

AFFECTED PERSONS

Throughout the review of this project, two entities sought and received affected person status under WAC 246-310-010:

- Legacy Health System on behalf of Legacy Salmon Creek Hospital located in Vancouver within Clark County; and
- Northwest Newborn Specialists, a physician group that specializes in neonatal medicine under a contract with hospitals.

During the reconsideration review of the SWMC application, both entities listed above submitted comments regarding this reconsideration review.

SOURCE INFORMATION REVIEWED-INITIAL

- Southwest Washington Medical Center's Certificate of Need Application received September 22, 2005
- Southwest Washington Medical Center's supplemental information dated November 18, 2005, January 11, 2006, and January 19, 2006
- Legacy Health System's November 11, 2005, response to the department's October 12, 2005, request for information
- Comments provided throughout the review of the project provided until February 8, 2006
- Legacy Health System's rebuttal comments received March 7, 2006
- Southwest Washington Medical Center's rebuttal comments received March 6, 2006
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Office of Hospital and Patient Data Systems (April 3, 2006)
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2002, 2003, and 2004 summaries)

SOURCE INFORMATION REVIEWED-INITIAL (continued)

- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Emergency and trauma designation data provided by the Department of Health's Office of Emergency Medical and Trauma Prevention
- Washington State Perinatal Levels of Care Criteria adopted by the Perinatal Advisory Committee--February 2005, used as guidance
- Data obtained from the Internet regarding health care worker shortages in Washington State
- Data obtained from the Internet regarding Southwest Washington Medical Center's project
- Data obtained from the Internet regarding mileage and distance
- Certificate of Need Historical files

SOURCE INFORMATION REVIEWED--RECONSIDERATION

- Southwest Washington Medical Center's Request for Reconsideration received May 17, 2006
- Southwest Washington Medical Center's Request for a Determination of Non-Reviewability received June 15, 2006
- Southwest Washington Medical Center's information submitted at the September 28, 2006, reconsideration public hearing
- Legacy Health System's information submitted at the September 28, 2006, reconsideration public hearing
- Northwest Newborn Specialists' information submitted at the September 28, 2006, reconsideration public hearing
- Southwest Washington Medical Center's rebuttal comments received October 13, 2006
- Legacy Health System's rebuttal comments received October 13, 2006
- Northwest Newborn Specialists' rebuttal comments received October 13, 2006
- Completed level III NICU Utilization Survey submitted by Legacy Health System on behalf of Salmon Creek Hospital
- Completed level II NICU Utilization Survey submitted by Peace Health St. John Medical Center

CRITERIA EVALUATION

To obtain Certificate of Need approval, Southwest Washington Medical Center must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).⁵

In its April 21, 2006, initial evaluation, the department concluded that SWMC's project did not meet the criteria under WAC 246-310-210 (need); WAC 246-310-220 (financial feasibility);

⁵ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240 (2) and (3).

246-310-230 (structure and process of care); and 246-310-240 (cost containment). This reconsideration evaluation will focus on information related to the sub-criteria previously denied under those criteria.⁶

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Southwest Washington Medical Center proposing to establish a neonatal intensive care unit (NICU) and level III obstetric services within space at the hospital is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

⁶ Under program rules, a project must demonstrate compliance with all relevant sub-criteria found in each criterion.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has not met the need criteria in WAC 246-310-210.

- (1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

For this reconsideration evaluation, the department will primarily use two data sources to assist in its review:

- Comprehensive Hospital Abstract Reporting System (CHARS) data; and
- Standards of Care guidelines outlined in the Washington State Perinatal Levels of Care Criteria.

Below is a brief summary of both data sources.

CHARS data

CHARS data is reported by each Washington State hospital to the department's Office of Hospital and Patient Data Systems. The CHARS data provides historical trends in discharges and lengths of stay for newborn patients for the major diagnostic category (MDC) #15 - NEWBORNS AND OTHER NEONATES WITH CONDITIONS ORIGINATING IN THE PERINATAL PERIOD. MDC #15 is made up of seven diagnosis related groups (DRGs)--385 through 391. The chart below provides the DRG and corresponding definition for MDC #15.⁷

DRG	Definition	Level of Care
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	Level III
386	EXTREME IMMATURITY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	Level III
387	PREMATURITY WITH MAJOR PROBLEMS	Levels II or III
388	PREMATURITY WITHOUT MAJOR PROBLEMS	Level II
389	FULL TERM NEONATE WITH MAJOR PROBLEMS	Level II
390	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	Levels I or II
391	NORMAL NEWBORN	Level I

As shown in the chart above, of the DRGs included in MDC #15, some do not correspond exactly with the level of care definitions. However, the majority of level III patients are included in DRGs 385 and 386, with a few level III patients in DRG 387.

As a provider of level II services, it is expected that SWMC would report a large number of discharges in DRGs 388 through 391. For DRGs 387 and 386, the department would expect a small number of discharges that would typically represent emergent patients or non-scheduled level III deliveries that present at SWMC and are unstable for transfer. For DRG 385, these patients are expected to be small and would represent patients that died or were transferred.

⁷ Each DRGs corresponding level of care is based on October 3, 2001, testimony provided by Louis Pollack, MD, a board certified neonatologist and member of Washington State Perinatal Advisory Committee.

Standards of Care guidelines outlined in the Washington State Perinatal Levels of Care Criteria

The Washington State Perinatal Level of Care Guidelines were initially developed in 1988, revised in 1993 and 2001, and reviewed in 2005. These guidelines were created to assist hospitals with obstetric and newborn care services to assess the type of patient best suited to their facility's capabilities and scope of care. The 2005 guidelines were adopted by the Perinatal Advisory Committee in February, and offer recommendations on facility and staffing standards for level III services. Within the guidelines, level II is separated into A and B and level III services are separated into A, B, and C. In both cases, A being the least intensive of services within the level and B (or C) as the most intensive.

The 2005 guidelines serve the same purposes as previous editions; that is, to outline general functions, patient descriptors, and resources for basic, intermediate and intensive care obstetrical and neonatal services. The document's primary objective is to provide clear definitions of perinatal-neonatal levels of care in Washington hospitals for use by clinical providers, health administrators, and state officials whose common goals are to

- improve the outcome of pregnancy;
- increase access to care for pregnant women and newborns; and
- optimize allocation of resources.

These goals call for the 2005 guidelines document to remain conservative. Each institution is encouraged to utilize the guidelines to assess and define its own scope of care. However, the guidelines do not mandate that an individual unit must provide the entire scope of service within a Level of Care designation, nor are they meant to rigidly limit the scope of services if appropriate resources are available. In addition, it is recognized that modifications may be necessary so that both the objectives of the document and the unique goals of a hospital or region may be met. For example, it is recognized that in some rural hospitals, the average daily census of neonates will be lower than that specified in the document in order to ensure access to care.

While the Standards of Care guidelines were not developed to be a regulatory document, the Certificate of Need Program uses the guidelines as a reference for hospitals applying for Level II (intermediate care nursery and obstetric services II) or Level III (neonatal intensive care nursery and obstetric services III) designations. In addition to these guidelines, the program's statute (RCW) and rules (WAC) must also be considered.

The Perinatal Levels of Care Criteria recommend that an applicant be providing the previous level of services before applying for the next higher level. Within the April 21, 2006, initial evaluation, the department concluded that SWMC met this recommendation.

Initial Evaluation Summary

Within its initial application, SWMC provided documentation intended to support the following assertions. [source: Initial evaluation, pp4-7]

- Using the service area of Clark and Skamania counties, SWMC asserted that the births had grown dramatically in each of the three levels of care.

- There was no level III NICU service for the Cowlitz-Wahkiakum service area.
- Based on the current and projected populations for Clark and Skamania counties, SWMC projected 163 discharges in year 2007, 168 in year 2008, 173, in year 2009, and 178 in year 2010.
- Based on the current and projected population of the service area of Clark and Skamania counties, SWMC projected need for 25 combined level II and level III beds in year 2007, which increased to 28 by the end of year 2010.
- By providing Level III services, SWMC would be able to avoid transferring patients which resulted in additional costs, medical risk to infants, and stress on families without evidenced-based improvements in health care outcome or cost reduction.
- SWMC was the primary provider of maternal, neonatal and early pediatric care for the medically indigent families in its service area. SWMC asserted that degrading its overall maternal fetal market share would impact its ability to provide a full range of services to the medically indigent in its service area.

Within its April 21, 2006, initial evaluation, the department concluded that the SWMC project did not meet this sub-criterion because SWMC failed to demonstrate that the population served or to be served had need for the project and other services and facilities of the type proposed would not or will not be sufficiently available or accessible to meet that need as required in WAC 246-310-210.

Reconsideration Evaluation

Within its reconsideration request, SWMC provided the following assertions. [source: SWMC reconsideration request received May 17, 2006, pp2-6]

- SWMC 2007 patient projections included in its CON application are significantly below 2006 actual admissions.
- The department erred in excluding Skamania County from SWMC's service area.
- The department's [April 21, 2006] decision failed to follow adopted procedures.
- Tertiary services are not limited to level III NICU care.
- The department failed to utilize accurate or request significant relevant information.
- The department has considered patient choice and combining services in a facility in the past.

In this reconsideration evaluation, the department will address each of these assertions.

SWMC 2007 patient projections included in its CON application are significantly below 2006 actual admissions [source: SWMC May 17, 2006, reconsideration request, p2]

Using the Clark and Skamania county services area, SWMC provided projections for its level III services which were summarized in a table within the initial evaluation. SWMC projected 163 level III patients in year 2007 without the proposed level III services. Once the level III services became available, it would serve 168 level III patients in year one (2008), and the number of patients would increase to 178 by the end of year three (2010).

SWMC states that its January 1, 2006, through May 1, 2006, patient counts for its “combined level II-III services”⁸ is 168. [SWMC reconsideration request, p2]

In response to SWMC’s assertion above, the affected person--Legacy Salmon Creek Hospital (LSCH)--notes that SWMC did not provide data to substantiate its assertion. Further, LSCH reviewed historical 2000-2005 CHARS data and determined that SWMC has historically experienced an average of 88 level III neonates annually, with the majority being in DRG 385--NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY. As a result, LSCH states that no growth or increasing trend in level III is discernable from the 2000-2005 historical CHARS data. [source: LSCH September 28, 2006, public hearing documents, pp2-4]

To assist in its review of this assertion, the department reviewed available CHARS data for SWMC for years 2000 through 2005 and January 1, 2006, through August 31, 2006. Tables IA and IB below show a breakdown of SWMC’s discharges for DRGs 385, 386, and 387. [source: CHARS data 2000 - August 31, 2006]

Table IA
Southwest Washington Medical Center
2000 through 2005 Number of Discharges Level III DRGs

Year	385	386	387	Total
2000	62	21	33	116
2001	83	17	43	143
2002	17	4	33	54
2003	87	10	10	107
2004	76	12	17	105
2005	75	7	15	97
Totals	400	67	151	618
Annual Average	66.6	11.8	25.1	103
Average/Month	5.5	0.93	2.1	8.58

Table IB
Southwest Washington Medical Center Number of Discharges
January 1, 2006 through August 31, 2006

Year	385	386	387	Total
2006	22	22	36	80
Average/Month	2.7	2.7	4.5	10

As shown in Table IA above, for DRGs 385, 386, and 387, SWMC discharged an annual average of 103 level III patients, which equates to a monthly average of 8.58. For the first 8 months of year 2006, SWMC discharged 80 level III patients, which equates to an average of 10 level III patients per month. Tables IA and IB assume that all patients discharged under DRG 387 would be level III patients, which is unlikely. The historical

⁸ Again SWMC indicates that it is providing level III services without the Certificate of Need authority to do so. This issue has been addressed in the “Applicability of Certificate of Need Law” section of this evaluation and will not be readdressed in this portion of this evaluation.

data shown above does not demonstrate that SWMC's 2006 actual numbers are on track to be significantly higher than the 2007 projections of 163 as asserted by SWMC.

The department erred in excluding Skamania County from SWMC's service area [source: SWMC May 17, 2006, reconsideration request, pp2-3]

Within its reconsideration request, SWMC contends that Skamania County should be included in the service area when determining need for its level III services. To support this assertion, SWMC cites RCW 70.38.115(2)(a) and (d) (ii) which state:

(2)(a) *"The need that the population served or to be served by such services has for such services"* and

(2)(d)(ii) *"the extent to which such proposed services will be accessible to all residents of the area to be served."*

SWMC further cites WAC 246-310-210(1), which states:

(1) *"The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need."*

SWMC contends that the department's initial evaluation excluded Skamania County residents from SWMC's historical patient discharges for years 2000-2004, which is contrary to RCW 70.38.115 because residents of Skamania County will be served by the SWMC project.

For clarification purposes, within its initial evaluation, the service area review conducted by the department did not exclude residents from Skamania County from SWMC's historical patient discharges for years 2000-2004 as asserted by SWMC above. SWMC's historical discharge data was not altered by the department in any way. Rather, a review of historical CHARS discharge data and Oregon State discharge data for MDC #15 revealed that a small percentage of Skamania and Wahkiakum County residents elect to obtain MDC #15 health care services at SWMC. Within its initial application, SWMC did not provide data to demonstrate that it intended to alter any current referral patterns for MDC #15 patients in those two counties. As a result, the department determined SWMC's level III service area to be Clark and Cowlitz counties, and did not project an increase in patient in-migration from Skamania or Wahkiakum counties for level III services at SWMC.

Within its public hearing documents and rebuttal comments, SWMC redefines its level III service area to Clark, Cowlitz, and Wahkiakum counties. [source: SWMC September 26, 2006, public hearing documents, pp2-4] Generally, for Certificate of Need purposes, the department has recognized Cowlitz and Wahkiakum counties as one combined service area. Wahkiakum County geography demonstrates that the communities in the county must travel either north to Ocean Beach Hospital in Pacific County or east to PeaceHealth St. John Medical Center in Cowlitz County for health services. Of the two options, PeaceHealth St. John Medical Center provides a larger scope of healthcare services. As a result, the department concludes that inclusion of both Cowlitz and Wahkiakum counties is reasonable for this review.

The department's [April 21, 2006] decision failed to follow adopted procedures [source: SWMC May 17, 2006, reconsideration request, pp3-4]

SWMC's assertions related to this issue focused on the inclusion of Skamania County as part of the SWMC service area for level III services. This issue was addressed above. For this reconsideration evaluation, SWMC and the department agree that the service area for SWMC's level III services is Clark, Cowlitz, and Wahkiakum counties.

Tertiary services are not limited to level III NICU care [source: SWMC May 17, 2006, reconsideration request, pp4-5]

SWMC's argument under this issue focuses on its existing level II services. SWMC argues that its existing level II services are considered tertiary services, and were ignored by the department when it denied SWMC's application to expand to level III services. SWMC further states that it is "*the most logical provider of cost-effective and efficient level III neonatal services in the area*" and that it "*will be negatively affected by [the department's] decision as its daily census will be impacted.*" SWMC asserts that the department's denial of this project would cause a decline in SWMC's level II daily census, which would in turn reduce the opportunities of staff to maintain their advance care skills that are required for SWMC's level II patients.

Level II services and level III services are each defined as tertiary health services. Under the provisions of WAC 246-310-020, a facility must obtain separate Certificates of Need for each of these services. For clarification purposes, the department's initial denial of SWMC's request for level III services should not, in any way, affect SWMC's ability to continue to provide level II services to its patients. Further, denial of level III services should not affect the ability of SWMC staff to reach or maintain its compliance with the Washington State Perinatal Level of Care standard and guidelines related to its existing level II services.

The department failed to utilize accurate or request significant relevant information [SWMC May 17, 2006, reconsideration request, pp5]

The department determined within its April 21, 2006, initial decision, a current capacity of level II and level III beds for Clark and Cowlitz counties to be a total of at least 36. This breakdown is as follows:

- LSCH in Clark County - 25
- PeaceHealth St. John Medical Center (St. John) in Cowlitz County - 1. The exact number was unknown by the department, however, in order to maintain its ability to provide level II services, St. John must have at least one level II bed.

SWMC argues that the LSCH count was incorrect based on material provided in LSCH's 2001 application to establish the hospital and level III services. Further, SWMC asserts that the department should have obtained an accurate count for St. John.

During the course of reconsideration, the department requested capacity and utilization information from both St. John and LSCH. Based on responses from that request, the

following acute care hospitals located in Clark and Cowlitz counties have the following capacity to provide services.⁹

Table II
Clark and Cowlitz County Level II and Level III Capacity

Name	County Location	Level II capacity	Level III capacity	Combined Capacity
LSCH	Clark	7	15	22
St. John	Cowlitz	6	0	6
SWMC (applicant)	Clark	18	0	18
Totals		31	15	46

All three hospitals listed above provide level I and level II OB services, which typically include DRGs 388 - 391, with portions of DRG 387. Currently, LSCH is the only provider of Certificate of Need approved level III services. As shown above, the correct service area capacity is 15 level III beds. The SWMC application requests establishment of a level III services. Therefore the capacity of level II services at each of the three hospitals is irrelevant to the evaluation of SWMC's application for level III services.

The department has considered patient choice and combining services in a facility in the past
Under this assertion, SWMC referenced the department's 1988 evaluation of SWMC's application to consolidate acute inpatient services by stating, *"This project would provide the LDRP [labor, delivery, recovery, post-partum] facilities preferred by most patients and would provide obstetric, pediatric and high level diagnostic services in one facility."* SWMC states that the department considered patient preference when determining need and found that providing multiple services at one facility is preferable.

Before evaluating this assertion by SWMC, below is a brief overview of the 1988 application and the entire quote within the department's evaluation. [source: May 6, 1988, evaluation of Southwest Washington Hospitals project]

The application submitted by Southwest Washington Hospitals included an extensive remodel, construction and consolidation project at its two acute care facilities in Vancouver--St. Joseph Community Hospital and Vancouver Memorial Hospital.¹⁰ At the time the application was submitted, St. Joseph Community Hospital had 243 licensed beds and Vancouver Memorial Hospital had 192 licensed beds, for a two-facility total of 435. Given that many of the acute care services were provided at both facilities, the Southwest Washington Hospitals application proposed to consolidate a number of services thereby reducing the number of beds at Vancouver Memorial, increasing the number of beds at St. Joseph Community Hospital, which resulted in consolidation of some acute care services within the county. Specific to OB services, the project description on page 4 of the department's 1988 evaluation states:

⁹ Wahkiakum County is included in the service area, however, there are no hospitals located in the county.

¹⁰ In 1988, both St. Joseph Community Hospital and Vancouver Memorial Hospital were operated by Southwest Washington Hospitals.

"[Southwest Washington] Hospitals indicated that the obstetric facility at Vancouver Memorial is aging and needs to be replaced. The obstetric service lacks sufficient beds where the patient labors, delivers, recovers and receives post-partum care in the same bed (LDRP beds). Also, pediatrics and high-level diagnostic services are located at St. Joseph so that mothers or infants who need these services have to be transport to St. Joseph for the services. [Southwest Washington] Hospitals indicated the above factors resulted in 491 mothers from Clark County delivering in Portland obstetric facilities in 1984. This project would provide the LDRP facilities preferred by most patients and would provide obstetric, pediatric, and high-level diagnostic services in one facility."

When the entire quotation is provided in context, it is clear that the quotation was simply a summary of the rationale provided in the application, rather than a conclusion reached by department in its evaluation of the 1988 project. The conclusion reached by the department for the 1988 project acknowledged that the majority of OB patients preferred to obtain services at St. Joseph Community Hospital, rather than Vancouver Memorial. Given that the Vancouver Memorial facility was outmoded and could not offer LDRP beds, all OB services were combined at the St. Joseph Community Hospital site. In fact, the 1988 approval relocated many services to the St. Joseph Community Hospital site, leaving the Vancouver Memorial site with 60 beds dedicated to alcohol treatment. This re-configuration was requested by Southwest Washington Hospitals. [source: May 6, 1988, evaluation of Southwest Washington Hospitals project, p7]

SWMC's comparison of the statement above to this application for level III services is not an "apples-to-apples" comparison. Patient choice by itself is not a review criterion. Further, patient choice does not create need. If need for a service has been demonstrated, then patient choice may be considered by the department when determining which applicant should fill the need if two or more applicants are competing to serve the need. As a result, the patient choice consideration does not surpass the criteria the program must consider under its rules. One of those factors that must be considered is WAC 246-310-210(1):

"The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need."

For projects requesting level III services, another consideration is the definition of "tertiary service" found in WAC 246-310-010:

"Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

Level III services are tertiary services as defined in WAC 246-310-020(1)(d)(i)(c). Consideration of sufficient patient volume to ensure quality outcomes is imperative when evaluating this project. As a result, all hospitals within a planning area may not be approved to provide all tertiary health services.

Within its initial application and again within its reconsideration documents, SWMC asserts that there is sufficient need projected to support two level III services within Clark County, and approval of its project would not be a duplication of services. In its initial evaluation, the department acknowledged that LSCH opened on August 15, 2005¹¹--39 days before SWMC submitted its initial project. LSCH began admitting patients into its neonatal intensive care unit (NICU) on August 22, 2005--32 days before SWMC submitted its application. At this time, LSCH's NICU is fully operational and accepting level III patients; however, it began by limiting admissions to infants with gestational ages ≥ 30 weeks, and gradually worked toward admissions of infants with gestational ages ≥ 28 weeks. [source: LSCH November 11, 2005, public comment] For level III services, this gradual, phased-in approach is generally the approach used by hospitals. This approach allows the NICU staff to build on education and skills, while consistently monitoring outcomes and making any adjustments as necessary; this is an approach that the department would expect. As of the writing of the initial evaluation, LSCH's hospital and NICU had been accepting patients for approximately 8 months, and had not reached nearly enough sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. As a result, in its initial evaluation, the department concluded that it would be unreasonable to approve a second level III NICU in the same service area when the first level III NICU had been in operation for less than a year. Such an approval would jeopardize the current provider from reaching utilization levels to optimize provider effectiveness and assure quality of care.

As of the writing of this reconsideration evaluation, LSCH has been in operation for approximately 15 months, and has begun reporting its hospital data to the department's Office of Hospital and Patient Data Systems. CHARS data for LSCH is available for its first 13 months of operation--August 2005 through August 2006. Table III below is a breakdown of LSCH's discharges for the level III DRGs--385, 386, and 387. [source: CHARS data, year end 2005 and 2006, January - August]

Table III
Legacy Salmon Creek Hospital Number of Discharges
August 2005 through August 2006

Year	385	386	387	Total
2005	0	5	6	11
2006	1	35	22	58
Total	1	40	28	69

As shown above, even if the department were to assume that all discharges under DRG 387 would qualify as level III, which is unlikely, LSCH discharged a total of 69 level III patients since it opened its doors in August 2005. Additionally, LSCH's average daily census (ADC) of its combined level II/III NICU¹² was 3.4 from the date of opening (August 2005) through March 31, 2006; its ADC increased to 6.8 from April 1, 2006 through August 31, 2006. [source: LSCH public hearing documents, p4] As a result, even if the department were to assume that all of the babies within LSCH's NICU were level III

¹¹ LSCH press release dated August 5, 2005.

¹² LSCH did not provide its ADC for level III separate from level II.

patients, which is unlikely, an ADC of 6.8 calculates to 45% utilization of the 15 level III beds.¹³

In conclusion, as with its initial evaluation, the department again recognizes that allowing LSCH to reach sufficient patient volumes is essential. As a result, SWMC has failed to demonstrate that the current provider of level III NICU services, also located in Vancouver, is neither available nor accessible. Further, SWMC has failed to demonstrate that establishment of its level III services would not be an unnecessary duplication of services in Clark County.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

In its April 21, 2006, initial evaluation, the department concluded that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently had access to services at SWMC. The department further noted that the addition of level III services at SWMC would not negatively affect patient access to the hospital or any other healthcare facility owned or operated by SWMC. There was no additional information provided during the reconsideration review that would change this conclusion by the department, therefore, this sub-criterion remains met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has not met the financial feasibility criteria in WAC 246-310-220.

- (1) The immediate and long-range capital and operating costs of the project can be met.
(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.
(3) The project can be appropriately financed.

In its April 21, 2006, initial evaluation, the department concluded that the project did not meet the financial feasibility criteria outlined in WAC 246-310-220 because need had not been demonstrated for a second level III provider in Clark County.

In the need portion of this reconsideration evaluation, the department continues to conclude that need for an additional level III provider in Clark County has not been demonstrated. Given this conclusion, the department's conclusions regarding the financial feasibility criteria remains unchanged, and this criterion is not met.

¹³ $6.8 / 15 = 0.4533$

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has not met the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.
- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.
- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.
- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

In its April 21, 2006, initial evaluation, the department concluded that the project did not meet the structure and process of care criteria outlined in WAC 246-310-230 because need had not been demonstrated for a second level III provider in Clark County.

In the need portion of this reconsideration evaluation, the department continues to conclude that need for an additional level III provider in Clark County has not been demonstrated. Given this conclusion, the department's conclusions regarding the structure and process of care criteria remains unchanged, and this criterion is not met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

In its April 21, 2006, initial evaluation, the department concluded that the project did not meet the cost containment criteria outlined in WAC 246-310-240 because need had not been demonstrated for a second level III provider in Clark County.

In the need portion of this reconsideration evaluation, the department continues to conclude that need for an additional level III provider in Clark County has not been demonstrated. Given this conclusion, the department's conclusions regarding the cost containment criteria remains unchanged, and this criterion is not met.